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EXAMINER

MCKANE, ELIZABETH L

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.



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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/746,990
Filing Date: December 22, 2000
Appellant(s): WU ET AL.

**MAILED
JAN 08 2008
GROUP 1700**

Andrew C. Farmer
For Appellant

SUPPLEMENTAL EXAMINER'S ANSWER

Responsive to the Remand under 37 CFR.41.50(a)(1) for reasons other than for further consideration of a rejection on November 2, 2007, a supplemental Examiner's Answer is set forth below:

This is in response to the appeal brief filed 29 January 2007 appealing from the Office action mailed 5 January 2006 and the Remand mailed 2 November 2007.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is incorrect. A correct statement of the status of the claims is as follows:

This appeal involves claims 1, 4, 6-10, 13, 15-17, and 20-28. Claim 26 has been indicated as being allowable.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

It is clear that the first paragraph of the Summary corresponds with independent claim 1. The second paragraph clearly corresponds to independent claim 13. Furthermore, the third paragraph clearly corresponds to independent claim 16.

(6) Grounds of Rejection to be Reviewed on Appeal

The unintentional omission of claim 10 from the Rejection Statement in numbered paragraph 7 of the Final Rejection was a typographical error only. The limitation of claim 10 was clearly addressed in this paragraph along with claims 8 and 9. The rejection of claim 10 is NOT a new ground of rejection. Note that claim 10 is listed as a rejected claim on the Office Action Summary of the Final Rejection.

WITHDRAWN REJECTIONS

The following grounds of rejection are not presented for review on appeal because they have been withdrawn by the examiner.

The rejection of claim 7 under 35 U.S.C. §112, second paragraph.

The rejection of claim 22 under 35 U.S.C. §103(a).

The appellant's statement of the grounds of rejection to be reviewed on appeal is substantially correct. The changes are as follows:

Claims 8-10 stand rejected under 35 U.S.C. §103(a) over Markham or Sackier et al..

The inclusion of claim 10 with claims 8 and 9 is correcting a typographical error only.

This is NOT a new ground of rejection.

Claim 20 stands rejected under 35 U.S.C. §103(a) over Schad and either Markham or Sackier et al., further in view of Moyers (U.S. Patent No. 6,090,213).

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

5,176,699	MARKHAM	1-1993
5,776,146	SACKIER et al.	7-1998
6,090,213	MOYERS	7-2000
5,935,537*	SCHAD	08-1999
WO 96/30058*	SCHAD	10-1996

*US 5,935,537 is the English language equivalent and 371 filing of WO 96/30058.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

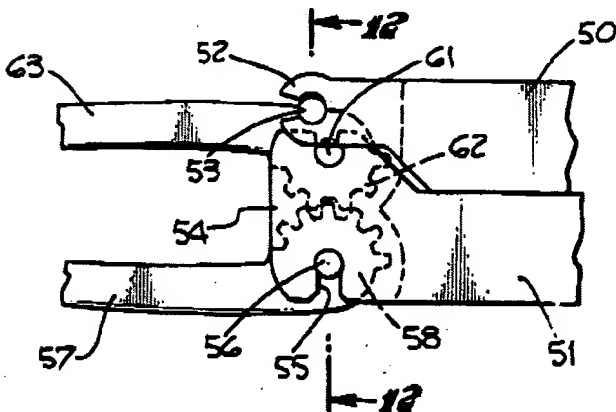
A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, 6, 13, 15, 21, and 23-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Markham (U.S. Patent No. 5,176,699).

Markham teaches a medical device (forceps) comprising a first surface (gear wheel) **58** and a second surface (gear wheel) **62**, the first and second surfaces being adjacent to each other in facing relationship and being rotatable with respect to one another, and each about a pivot point



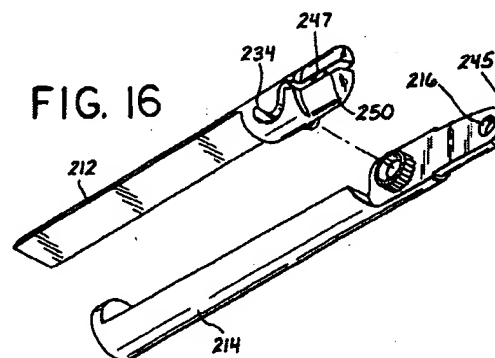
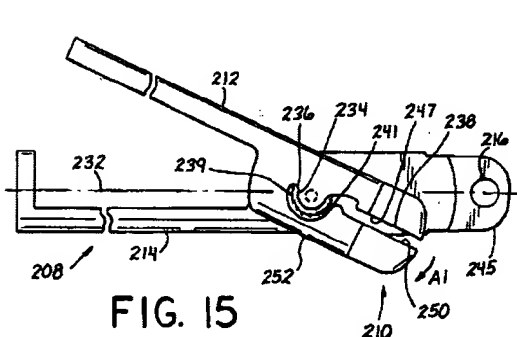
and having a contact area therebetween adjacent the pivot point. The contact area comprises a plurality of regular, straight, parallel, grooved projections/lines (e.g. gear teeth) on both the first and second part. To further clarify, the first surface is the rounded surface of the first gear wheel **58** from which the gear teeth extend

outwardly. Similarly, the second surface is the rounded surface of the second gear wheel **62** from which the gear teeth extend outwardly. The gear teeth are the projections which are in contact at the contact point between the gears. With respect to the limitation that the projections are “adapted to allow a fluid to flow around said projections” or “adapted to promote flow of fluid between the surfaces at the contact area,” it has been held that the recitation that an element is “adapted to” perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. In re Hutchison, 69 USPQ 138. The Examiner submits that the “projections” of Markham will permit fluid flow

therebetween and most certainly will promote flow better than two flat surfaces in contact. As to the device being reusable or disposable, these limitations do not define the device structurally over the device of Markham as the forceps of Markham are certainly capable of being either.

Claims 1, 4, 6, 13, 15, and 23-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Sackier et al. (U.S. Patent No. 5,776,146).

Sackier et al. discloses a medical device (surgical clamp/holder) having a first surface (pawl) 243 on first jaw 212 and a second surface (ratchet wheel) 239 on second jaw 214, the first and second surfaces being adjacent to each other in facing relationship and being rotatable with



respect to one another about a pivot point and having a contact area therebetween adjacent the pivot point. The contact area comprises a plurality of regular, straight, parallel, grooved projections/lines. To clarify, the first surface is the curved surface of the pawl, which is disclosed to have a plurality of teeth extending therefrom. The second surface is the curved surface of the ratchet wheel, which is disclosed to have a plurality of teeth extending therefrom. See col.9, lines 48-67. The projections are the teeth, one set of which are shown in Figures 15 and 16. Moreover, with respect to the limitation that the projections are “adapted to allow a fluid to flow around said projections” or “adapted to promote flow of fluid between the surfaces at the

contact area," it has been held that the recitation that an element is "adapted to" perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. In re Hutchison, 69 USPQ 138. The Examiner submits that the "projections" of Sackier et al. will permit fluid flow therebetween and most certainly will promote flow better than two flat surfaces in contact. As to the device being reusable or disposable, these limitations do not define the device structurally over the device of Sackier et al. as the surgical clamp of Sackier et al. is certainly capable of being either.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Markham or Sackier et al..

The unintentional omission of claim 10 from the Rejection Statement in numbered paragraph 7 of the Final Rejection was a typographical error only. The limitation of claim 10 was clearly addressed in this paragraph along with claims 8 and 9. The rejection of claim 10 is NOT a new ground of rejection. Note that claim 10 is listed as a rejected claim on the Office Action Summary of the Final Rejection.

Markham and Sackier et al. are silent with respect to the material from which the medical devices are fabricated. However, although not specifically disclosed by Markham and Sackier et al, it is deemed obvious to fabricate the medical devices from non-reactive metals (e.g. surgical grade stainless steel) and polymers, as is well-known in the art.

Claims 16, 17, 27, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schad (WO 96/30058, see English translation) in view of either Markham or Sackier et al..

Schad teaches a method of cleaning and disinfecting jawed surgical instruments, such as forceps and endoscopic instruments, within a chamber wherein the instruments are contacted with a cleaning/disinfecting fluid within a vessel 4 while being oscillated. See English translation, page 2, lines 12-19 and page 3, lines 14-22. The method achieves a surgical instrument suitable for reuse. Although Schad does not disclose that the instruments have a plurality of projections on a contact area at the pivot point of the jaw, both of Markham and Sackier et al. evidence that this is the common configuration found in jawed medical instruments. Therefore, it would have been obvious to employ the method of Schad to clean and disinfect the jawed surgical instruments of the prior art, as it has been shown to be effective in cleaning such.

With respect to circulating the fluid in the vessel 4, Schad discloses that the fluid is hot steam of about 120 °C (translation, page 7, lines 3-8). It would have been obvious to circulate the steam within the vessel during the step of contacting, in order to equalize the sterilization temperature within the vessel thereby assuring that the forceps achieves the sterilization temperature. Moreover, with respect to flowing the fluid around the projections, Schad teaches

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that the hot steam penetrates deep into a surgical instrument and reaches the most inaccessible places thereof. See translation, page 2, line 20 to page 3, line 5. Thus, such a step would have been intrinsic in the method of Schad.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schad and either Markham or Sackier et al. as applied to claim 16 above, and further in view of Moyers (US 6,090,213).

The combination of Schad with either of Markham or Sackier et al. fails to teach reducing a pressure in the vessel. Moyers, however, discloses a method of cleaning endoscopic implements wherein after cleaning a vacuum is pulled on the chamber in combination with the application of hot air in order to remove all moisture from the implements. See col.3, line 31 to col.4, line 5. Since Schad discloses that the sterilized instruments are dried by application of hot air (translation, page 7, lines 16-18), it is deemed obvious to also apply a vacuum, in the manner of Moyers in order to shorten the drying time.

Allowable Subject Matter

Claims 7, 22, and 26 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter:

With respect to claim 7, neither of Markham nor Sackier et al. disclose a connector housing or a

luer lock. As to claim 22, both Markham and Sackier et al. teach projections on both the first and second part of the contact area. With respect to claim 26, in the medical device of Markham, both the first and second part carry grooves. However, the grooves on the first part are not in registry with the grooves in the second part, since the first and second part form a gear. In a gear, the grooves on one part must register with the projections of the second part.

(10) Response to Argument

A. The rejection of claim 7 under 35 U.S.C. §112, second paragraph, was improper.

The Examiner has withdrawn the rejection of claim 7.

B. The rejection of claims 1, 4, 6, 13, 15, 21 and 23 to 25 under 35 U.S.C. §102(b) over the Markham U.S. Patent No. 5,176,699 was improper.

On page 4 of the Brief, Appellant argues that Markham fails to anticipate the claimed invention – specifically, that the gear teeth “are not on the surfaces in facing relationship, and further they are not adapted to allow a fluid to flow around them to enhance cleaning and sterilization of the facing surfaces.” However, as set forth in the rejection of the claims, the gear teeth extend from the surfaces of the gear wheels. The gear wheels are the two surfaces which are in facing relationship to each other and their respective gear teeth are in contact at a point adjacent the pivot points. Moreover, the Examiner maintains that the projections/gear teeth of

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Markham will permit fluid flow therebetween and most certainly will promote flow better than two flat surfaces in contact.

C. The rejection of claims 1, 4, 6, 13, 15, 22 to 25 under 35 U.S.C. §102(b) over the Sackier et al. U.S. Patent No. 5,776,146 was improper.

On page 5 of the Brief, Appellant asserts that Sackier et al. fail to anticipate the claimed invention because the surfaces in Sackier et al. “which are in facing relationship lack projections” and “are not adapted to allow a fluid to flow around them to enhance cleaning and sterilization of the facing surfaces.” Appellant explains that the ratchet teeth are not on the surfaces in facing relationship. However, the surfaces are the ratchet wheel and the pawl. These two surfaces are in facing relationship and moreover, they further include projections (teeth) which are in contact with each other. As set forth above, the projections/ teeth of Sackier et al. will permit fluid flow therebetween and most certainly will promote flow better than two flat surfaces in contact.

D. The rejection of claims 8 and 9 under 35 U.S.C. §103(a) over Markham or Sackier et al.. was improper.

Appellant also argues on page 5 of the Brief that neither Markham or Sackier et al. teach opposing faces with projections thereon. However, as set forth in the claim rejections, both of Markham and Sackier et al. teach facing surfaces with projections thereon.

The Examiner's inclusion of claim 10 with claims 8 and 9 is correcting a typographical error only. This is NOT a new ground of rejection.

E. The rejection of claims 16, 17, 27 and 28 under 35 U.S.C. §103(a) over Schad (WO 96/30058) in view of either Markham or Sackier et al.. is improper.

Continuing on page 5 of the Brief, Appellant argues that "Schad appears singularly unsuited to cleaning either of the instruments depicted by Markham and Sackier et al." since "Schad holds a round instrument" for sterilization. However, Schad does not sterilize a round instrument at all. Appellant appears to be referencing Figure 2 of Schad wherein the end of a surgical instrument 1 is shown being held within holder 9. This is merely a cross-section of the element, as described in the Brief Description of the Drawings. The surgical instrument is not, in fact, round. It is a jawed surgical instrument, such as a surgical forceps, as further illustrated in Figure 1. See also page 1, lines 12-14 and page, lines 1-5 of the English translation wherein it is disclosed to sterilize jawed surgical instruments. These are they same types of instruments being taught by both Markham and Sackier et al..

Addressing claim 17 particularly, Appellant alleges that because Schad "changes the orientation of the entire device," the reference must not "teach moving the parts of the device." However, it is noted that the claim does not require that the two parts be moved with respect to each other. Claim 17 requires only "moving at least one of said at least two parts of said medical device" – as Schad teaches oscillating the entire medical device during cleaning, both of the first and second parts are moved during cleaning. Thus, Schad meets this claim limitation.

F. The rejection of claim 20 under 35 U.S.C. §103(a) over Schad, Moyers and either Markham or Sackier et al.. was improper.

On page 6 of the Brief, Appellant submits that that Moyers “does not draw a vacuum to vaporize fluid and does not draw sufficient vacuum for such purpose.” This statement amounts to no more than mere speculation. Regardless, in col.3, lines 45-52, Moyer discloses that the eductors pull a vacuum and that the “eductors 94 and 96 can exhaust air or any other gas used and any moisture” (emphasis added). The examiner submits that the vacuum drawn in Moyers is sufficient to assist in the vaporization of the liquid left in the instruments that have been cleaned.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner’s answer.

Appellant may file a reply brief in compliance with 37 CFR 41.41 within two months of the date of mailing of this supplemental examiner’s answer. Extensions of time under 37 CFR 1.136(a) are not applicable to this two month time period. See 37 CFR 41.43(b)-(c).

A Technology Center Director or designee has approved this supplemental examiner’s answer by signing below:


GREGORY MILLS
QUALITY ASSURANCE SPECIALIST

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For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Elizabeth Leigh McKane

Elizabeth Leigh McKane

Conferees:

/Gladys JP Corcoran/
Supervisory Patent Examiner, Art Unit 1797

for *[Signature]* *Romulo Delmonte, Acting Appeals Specialist*
Jennifer K. Michener